

Notice of Allowability

Application No.

10/814,801

Examiner

Sharon E. Kennedy

Applicant(s)

DIONNE ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE filed on June 20, 2006, new prior art, petition decision of July 26, 2006.
2. ☒ The allowed claim(s) is/are 1-24.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>6/20/06; 6/29/06</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Drawings

The drawings filed 03/31/2004 are acceptable to the examiner.

Allowable Subject Matter

Claims 1-24 are allowed.

The following is an examiner's statement of reasons for allowance: New prior art is cited for consideration before the examiner. In addition, there is a petition decision of July 26, 2006 which permits this application to now move forward.

Note is made of the International Search Report dated November 22, 2004 and the references cited therein. These references have been studied, particularly the passages cited, however, none of the references disclose the osmotic pump having the vent and semipermeable membrane being capable of displacement upon reaching a threshold pressure.

The patent to Carr et al., US 6,508,808, has already been discussed by the examiner in the previous office action. The patent to Dionne, US 6,132,420, was already considered by the examiner and is listed in the first PTO-1449. The patent to Harper et al., US 6,436,091, discloses an implantable osmotic device for long-term use. With reference to figure 2, Harper discloses a plurality of openings 216 covered by a semipermeable membrane 214, which is in turn covered by an impermeable barrier 220. The barrier 220 may be breached by a physician after implantation by needle 222. Note figure 3 and the various barrier configurations in sheet 2. This patent does not

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show a semipermeable membrane responsive to a threshold pressure in the osmotic pump as set forth in the independent claims.

The patent to Balaban et al., US 5,308,348, discloses a delivery device having osmotic agent 15, movable piston 17, drug exit orifice 91 covered by, for example, resilient band 21. The band is sufficiently tight to seal the orifice, but is capable of being stretched by the force of the moving partition 17 (transmitted through the beneficial agent) to separate sufficiently from the orifice to permit escape of the beneficial agent. Once the force is spent, the band once again seats against the orifice, thus providing the pulsatile delivery. This patent does not show the vent as claimed. The band is not a semipermeable membrane. Further, the osmotic agent is not vented out of pump or released in anyway as required by the independent claims.

Regarding Brown et al., WO 02/43800, this reference discloses a plug 10 for use with an osmotic delivery device having an expansion control channel which accommodates the thermal expansion of a drug formulation, which may optionally contain a frit. Figure 5 shows drug entrance port 35, spiraled expansion control channel 21, frit 50 and outlet 45. Sheet 6/11 shows the assembly of the device and the compression of air 5. This reference does not show the claimed embodiments, including a semipermeable membrane responsive to a threshold pressure, in combination with the other elements.

The advantages of this device over the prior art were discussed in detail by the examiner in the previous Notice of Allowance. The remaining undiscussed cited prior

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art is less relevant and no comment is deemed necessary. Accordingly, this application is again allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon E. Kennedy
Primary Examiner
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